



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: E. Farber                      Examiner: Not assigned  
Serial No.: 09/991,117                      Group Art Unit: 1619  
Filed: November 13, 2001                      Docket: 14358-315  
Due Date: N/A                                  Date Mailed: February 11, 2002  
Title: ALLANTOIN-CONTAINING SKIN CREAM

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on February 11, 2002.

By:   
Name: Joy Johnson

**INFORMATION DISCLOSURE STATEMENT**

Honorable Commissioner  
for Patents  
Washington, DC 20231

Dear Sir:

This document is an Information Disclosure Statement to the above-cited patent application.

Attached hereto is at least one Form PTO-1449 listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b) the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

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It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.56, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned so that any deficiencies can be remedied.

This Information Disclosure Statement is being submitted before the mailing of an Office Action on the merits on the above-identified application. Therefore, no fee is due for submission of this Supplemental Information Disclosure Statement, pursuant to 37 C.F.R. § 1.97(b)(3).

A copy of each document is enclosed. Some of the documents may have markings thereon. No significance is meant to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) represented on any patent which may issue on the application. Applicants respectfully request that copies of the PTO-1449 forms, as considered and initialed by the Examiner, be returned with the next communication.

U.S. Patent No. 3,830,824 to Margraf, issued August 20, 1974.

U.S. Patent No. 3,830,825 to Margraf, issued August 20, 1974.

U.S. Patent No. 3,830,908 to Klippe et al., issued August 20, 1974.

U.S. Patent No. 3,856,805 to Margraf, issued December 24, 1974.

U.S. Patent No. 3,930,000 to Margraf, issued December 30, 1975.

U.S. Patent No. 3,932,627 to Margraf, issued January 13, 1976.

U.S. Patent No. 3,954,989 to Mecca, issued May 4, 1976.

U.S. Patent No. 4,170,229 to Olson, issued October 9, 1979.

U.S. Patent No. 4,278,664 to Van Cleave, issued July 14, 1981.

U.S. Patent No. 4,374,766 to Puchalski et al., issued February 22, 1983.

U.S. Patent No. 4,670,263 to Noorlander, issued June 2, 1987.

U.S. Patent No. 4,707,354 to Garlen et al., issued November 17, 1987.

U.S. Patent No. 4,708,813 to Snyder, issued November 24, 1987.

U.S. Patent No. 4,806,262 to Snyder, issued February 21, 1989.

U.S. Patent No. 4,880,621 to Grollier et al., issued November 14, 1989.

U.S. Patent No. 4,981,845 to Pereira, issued January 1, 1991.

U.S. Patent No. 5,112,886 to Phalangas, issued May 12, 1992.

U.S. Patent No. 5,122,533 to Bar-On et al., issued June 16, 1992.

U.S. Patent No. 5,221,533 to Perlman, issued June 22, 1993.

U.S. Patent No. 5,455,033 to Silverman et al., issued October 3, 1995.

U.S. Patent No. 5,512,200 to Garcia, issued April 30, 1996.

U.S. Patent No. 5,567,427 to Papadakis, issued October 22, 1996.

U.S. Patent No. 5,578,312 to Parrinello, issued November 26, 1996.

U.S. Patent No. 5,616,347 to Alliger et al., issued April 1, 1997.

U.S. Patent No. 5,658,559 to Smith, issued August 19, 1997.

U.S. Patent No. 5,661,170 to Chodosh, issued August 26, 1997.

U.S. Patent No. 5,736,128 to Chaudhuri et al., issued April 7, 1998.

U.S. Patent No. 5,824,666 to Deckner et al., issued October 20, 1998.

U.S. Patent No. 5,827,870 to Chodosh, issued October 27, 1998.

U.S. Patent No. 5,830,483 to Seidel et al., issued November 3, 1998.

U.S. Patent No. 5,863,548 to Elder, issued January 26, 1999.

U.S. Patent No. 5,871,754 to Briggs et al., issued February 16, 1999.

U.S. Patent No. 5,876,736 to Cohen et al., issued March 2, 1999.

U.S. Patent No. 5,885,581 to Massand, issued March 23, 1999.

U.S. Patent No. 5,914,116 to Suares et al., issued June 22, 1999.

U.S. Patent No. 5,932,228 to Hall et al., issued August 3, 1999.

U.S. Patent No. 5,952,373 to Lanzendörfer et al., issued September 14, 1999.

U.S. Patent No. 5,958,436 to Hahn et al., issued September 28, 1999.

U.S. Patent No. 6,060,061 to Breton et al., issued May 9, 2000.

U.S. Patent No. 6,080,393 to Liu et al., issued June 27, 2000.

U.S. Patent No. 6,120,782 to Mansouri, issued September 19, 2000.

EPO Publication No. 0242553 by Campo, published October 28, 1987.

EPO Publication No. 0380157 by Weisberg, published August 1, 1990.

PCT Publication No. WO 90/09779 by Benhuri, published September 7, 1990.

Great Britain Patent No. 1,346,544 to Margraf, issued February 13, 1974.

Japanese Patent No. JP 358140013A to Dai Ichi Seiyaku et al. (inventors Kuroda et al.), issued August 19, 1983 (translated from Japanese).

English-language abstract of a Japanese patent publication, Japan Patent Publication No. JP 404208219 by Abe et al., published July 29, 1992 (abstract only).

Product information insert for Alphosyl Cream and Alphosyl Lotion, G.D. Searle (South Africa), April 24, 1975.

Product information insert for Clearasil Medicated Facial Cleanser, Procter & Gamble (South Africa), January 31, 1994.

Product information insert for Arola Rosebaum Ointment, Supramed Limited, January 12, 1986.

Abstract of a publication, M. Cajkovac et al., "Influence of Emulsoid Vehicle on the Release and Activity of Allantoin," Pharmazie 47: 39-43 (1992) (abstract only).

Abstract of a publication, M. Maragakis et al., "Possibilities of Scar Treatment After Thoracic Surgery," Drugs Under Exp. & Clin. Res. 21: 199-206 (1995) (abstract only).

Product information insert for Alphosyl, undated.

Abstract of a publication, G. Stinco et al., "Seborrheic Dermatitis Treated with Furalglucitole Cream," Dermatol. Clin. 18: 78-81 (1998) (abstract only).

Abstract of a publication, G.H. Willital & H. Heine, "Efficiency of Contractubex® Gel in the Treatment of Fresh Scars After Thoracic Surgery in Children and Adolescents," Int. J. Clin. Pharmacol. Res. 14: 193-202 (1994) (abstract only).

H.W. Margraf & T.H. Covey, Jr., "A Trial of Silver-Zinc-Allantoinate in the Treatment of Leg Ulcers," Arch. Surg. 12: 699-704 (1977).

Remington: The Science and Practice of Pharmacy (19<sup>th</sup> Ed. 1995, Mack Publishing Co. Easton, Pennsylvania), pp. 639-640, 1380.

D. Hoffmann, "The Complete Illustrated Herbal," (Barnes and Noble, 1996), pp. 63, 104.

F.R. Greenbaum. "The Story of Allantoin," Am. J. Pharm. 112: 205-216 (1940).

M.A. Lesser, "Allantoin," Drug Cosmet. Ind. 42: 451-456, 469 (1938).

I.I. Lubowe & S.B. Mecca, "Allantoin and Aluminum Derivatives in Dermatological Applications," Drug Cosmet. Ind. 84: 36, 37, 117 (1959).

S.B. Mecca, "Allantoin and the Newer Aluminum Allantoinates," Proc. Scient. Sect. Toilet Goods Assoc. No. 31: 1-6 (1959).

S.B. Mecca, "The Function and Applicability of the Allantoins," Proc. Scient. Sect. Toilet Goods Assoc. No. 39: 7-15 (1963).

P. LeVan et al., "The Use of Silicones in Dermatology," Calif. Med. 81: 210-213 (1954).

R. Cahen & A. Pessonniere, "Etude Pharmacologique de L'Allantoïnate de Dihydroxyaluminium et de L'Allantoïnate de Chlorhydroxyaluminium. I.-- Toxicité," Ann. Pharm. Franc. 20: 623-636 (1962) (in French), discloses the physical and chemical properties and the toxicity of dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate. The compounds were observed to have no toxicity.

R. Cahen & J.-F. Clement, "Etude Pharmacologique de L'Allantoïnate de Dihydroxyaluminium et de L'Allantoïnate de Chlorhydroxyaluminium. II.--Etude de l'Activité

Gastrique," Ann. Pharm. Franç. 20: 693-703 (1962) (in French), discloses the activity of dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate on gastric activity. The compounds were found to have acid-neutralizing and buffering activity and to diminish gastric acidity.

R. Cahen & A. Pessonniere, "Etude Pharmacologique de L'Allantoïnate de Dihydroxyaluminium et de L'Allantoïnate de Chlorhydroxyaluminium. III.--Effet Anti-ulcérage," Ann. Pharm. Franç. 20: 704-713 (1962) (in French), discloses the anti-ulcer activity of the compounds dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate. The compounds were found to have anti-ulcer activity in rats and guinea pigs comparable to compounds such as aluminum hydrate and bismuth subnitrate.

R. Cahen & A. Pessonniere, "Etude Pharmacologique de L'Allantoïnate de Dihydroxyaluminium et de L'Allantoïnate de Chlorhydroxyaluminium. IV.--Effet sur l'Ulcère Médicamenteux Expérimental," Ann. Pharm. Franç. 21: 215-222 (1963) (in French), discloses the effect of the compounds dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate on ulcers produced in the rat by administration of phenylbutazone or reserpine. The compounds were found to have activity against such ulcers.

C. Debray et al., "Etude de Dérivés Allantoïniques de l'Aluminium dans la Thérapeutique des Affections Gastro-duodénales," Presse Méd. 70: 2643-2644 (1962) (in French) discloses the activity of the compounds dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate administered in a complex with a polymer of polyoxyethylene and polyoxypropanediol, methylhomatropine bromide, and calcium carbonate.

USSN 09/991,117

Docket No. 14358-315

on gastrointestinal conditions. The complex was said to be effective against duodenal ulcer and effective in protecting the gastric mucosa.

Respectfully submitted,

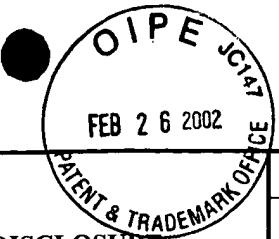


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Dated: February 11, 2002

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Substitute for form 1449A/PTO				Complete if Known	
				Application Number	09/991,117
				Filing Date	November 13, 2001
				First Named Inventor	E. Farber
				Art Unit	1619
				Examiner Name	Not yet assigned
Sheet	1	of	4	Attorney Docket Number	14358-315

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U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number -Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-3,830,824	08/20/74	Margraf
		US-3,830,825	08/20/74	Margraf
		US-3,830,908	08/20/74	Klippen et al.
		US-3,856,805	12/24/74	Margraf
		US-3,930,000	12/30/75	Margraf
		US-3,932,627	01/13/76	Margraf
		US-3,954,989	05/04/76	Mecca
		US-4,170,229	10/09/79	Olson
		US-4,278,664	07/14/81	Van Cleave
		US-4,374,766	02/22/83	Puchalski et al.
		US-4,670,263	06/02/87	Noorlander
		US-4,707,354	11/17/87	Garlen et al.
		US-4,708,813	11/24/87	Snyder
		US-4,806,262	02/21/89	Snyder
		US-4,880,621	11/14/89	Grollier et al.
		US-4,981,845	01/01/91	Pereira

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		EPO Publication No. 0242553	10/28/87	Campo	
		EPO Publication No. 0380157	08/01/90	Weisberg	
		PCT Publication No. WO 90/09779	09/07/90	Benhuri	
		Great Britain Patent No. 1,346,544	02/13/74	Margraf	
		Japanese Patent No. JP 358140013A	08/19/83	Kuroda et al. (Dai Ichi Seiyaku et al.) translated	
		Japan Patent Publication No. JP 404208219 English abstract	07/29/92	Abe et al. (abstract only)	

Examiner Signature		Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.



Substitute for form 1449B/PTO

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	09/991,117
Filing Date	November 13, 2001
First Named Inventor	E. Farber
Group Art Unit	1619
Examiner Name	Not yet assigned

Attorney Docket Number 14358-315

Sheet 2 of 4

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## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number -Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-5,112,886	05/12/92	Phalangas
		US-5,122,533	06/16/92	Bar-On et al.
		US-5,221,533	06/22/93	Perlman
		US-5,455,033	10/03/95	Silverman et al.
		US-5,512,200	04/30/96	Garcia
		US-5,567,427	10/22/96	Papakadis
		US-5,578,312	11/26/96	Parrinello
		US-5,616,347	04/01/97	Alliger et al.

## OTHER PRIOR ART – NONPATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Product information insert for Alphosyl Cream and Alphosyl Lotion, G.D. Searle (South Africa), April 24, 1975	
		Product information insert for Clearasil Medicated Facial Cleanser, Procter & Gamble (South Africa), Jan. 31, 199	
		Product information insert for Arola Rosebaum Ointment, Supramed Limited, Jan. 12, 1986	
		Abstract of a publication, M. Cajkovac et al., "Influence of Emulsoid Vehicle on the Release and Activity of Allantoin," <u>Pharmacie</u> 47:39-43 (1992) (abstract only)	
		Abstract of a publication, M. Maragakis et al., "Possibilities of Scar Treatment After Thoracic Surgery," <u>Drugs Under Exp. &amp; Clin. Res.</u> 21:199-206 (1995) (abstract only)	
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		Abstract of a publication, G.H. Willital & H. Heine, "Efficiency of Contractubex® Gel in the Treatment of Fresh Scars After Thoracic Surgery in Children and Adolescents," <u>Int. J. Clin. Pharmacol. Res.</u> 14:193-202 (1994) (abstract only)	
		H.W. Margraf & T.H. Covey, Jr., "A Trial of Silver-Zinc-Allantoinate in the Treatment of Leg Ulcers," <u>Arch. Surg.</u> 12:699-704 (1977)	
		Remington: The Science and Practice of Pharmacy (19 <sup>th</sup> Ed. 1995, Mack Publishing Co., Easton, Pennsylvania), pp. 639-640, 1380	
		D. Hoffmann, "The Complete Illustrated Herbal," (Barnes and Noble, 1996), pp. 63, 104	
		F.R. Greenbaum, "The Story of Allantoin," <u>Am. J. Pharm.</u> 112:205-216 (1940)	
		M.A. Lesser, "Allantoin," <u>Drug Cosmet. Ind.</u> 42:451-456, 469 (1938)	

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 3 of 4

Complete if Known	
Application Number	09/991,117
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First Named Inventor	E. Farber
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**U.S. PATENT DOCUMENTS**

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		US-5,658,559	08/19/97	Smith
		US-5,661,170	08/26/97	Chodosh
		US-5,736,128	04/07/98	Chaudhuri et al.
		US-5,824,666	10/20/98	Deckner et al.
		US-5,827,870	10/27/98	Chodosh
		US-5,830,483	11/03/98	Seidel et al.
		US-5,863,548	01/26/99	Elder
		US-5,871,754	02/16/99	Briggs et al.
		US-5,876,736	03/02/99	Cohen et al.

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		I.I. Lubowe & S.B. Mecca, "Allantoin and Aluminum Derivatives in Dermatological Applications," <u>Drug Cosmet. Ind.</u> 84:36, 37, 117 (1959)	
		S.B. Mecca, "Allantoin and the Newer Aluminum Allantoinates," <u>Proc. Scient. Sect. Toilet Goods Assoc.</u> No. 31: 1-6 (1959)	
		S.B. Mecca, "The Function and Applicability of the Allantoins," <u>Proc. Scient. Sect. Toilet Goods Assoc.</u> No. 39: 7-15 (1963)	
		P. LeVan, "The Use of Silicones in Dermatology," <u>Calif. Med.</u> 81:210-213 (1954)	
		R. Cahen & A. Pessonner, "Etude Pharmacologique de L'Allantoinate de Dihydroxyaluminium et de L'Allantoinate de Chlorhydroxyaluminium. I.-- Toxicité," <u>Ann. Pharm. Franc.</u> 20: 623-636 (1962) (in French), discloses the physical and chemical properties and the toxicity of dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate. The compounds were observed to have no toxicity.	
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				Group Art Unit	1619
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Sheet	4	of	4	Attorney Docket Number	14358-315

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		US-6,060,061	05/09/00	Breton et al.
		US-6,080,393	06/27/00	Liu et al.
		US-6,120,782	09/19/00	Mansouri
		US-		

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		R. Cahen & A. Pessonniere, "Etude Pharmacologique de L'Allantoinate de Dihydroxyaluminium et de L'Allantoinate de Chlorhydroxyaluminium. III.--Effet Anti-ulcereux," <i>Ann. Pharm. Franc.</i> 20: 704-713 (1962) (in French), discloses the anti-ulcer activity of the compounds dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate. The compounds were found to have anti-ulcer activity in rats and guinea pigs comparable to compounds such as aluminum hydrate and bismuth subnitrate.	
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		C. Debray et al., "Etude de Dérivés Allantoiniques de l'Aluminium dans la Thérapeutique des Affections Gastro-duodénales," <i>Presse Méd.</i> 70: 2643-2644 (1962) (in French) discloses the activity of the compounds dihydroxyaluminum allantoinate and chlorhydroxyaluminum allantoinate administered in a complex with a polymer of polyoxyethylene and polyoxypropanediol, methylhomatropine bromide, and calcium carbonate on gastrointestinal conditions. The complex was said to be effective against duodenal ulcer and effective in protecting the gastric mucosa.	

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